

REMARKS

This Amendment is in response to the Office Action dated September 8, 2009 ("Office Action"). It is respectfully submitted that the application is in condition for allowance. Claims 31-37 are pending. Claims 10-19 and 29-30 have been cancelled; and claims 34-37 have been added by virtue of the present amendment. No new matter has been added. Allowance and reconsideration of the application in view of Applicants' amendment and the ensuing remarks are respectfully requested.

The Specification has been amended to demarcate the trademarks, TAQMAN®, AMPLITAQ GOLD®, and GIBCO®.

Claim 34 has been added and recites particular dosages of R-etodolac. No new matter is added. Support may be found throughout the specification and original claim 15.

Claim 35 has been added and recites particular dosages of recombinant humanized monoclonal antibody 2C4. No new matter is added. Support for this amendment may be found throughout the specification and original claim 16.

Claim 36 has been added and recites particular routes of administration. No new matter is added. Support may be found throughout the specification and original claim 19.

Claim 37 has been added and recites a method of treating prostate cancer, similar to claim 31, comprising "providing a quantity of R-etodolac and a quantity of a recombinant humanized monoclonal antibody 2C4 to said mammal; administering the quantity of R-etodolac; and administering the quantity of the recombinant humanized monoclonal antibody 2C4 to said mammal." No new matter is added. Support may be found throughout the specification.

Restriction Requirement

In the Office Action, the Examiner deemed the Restriction Requirement of April 15, 2008 proper because the Examiner now alleges that Hedvat *et al.* is prior art under §102(a). The Examiner acknowledged Applicants' election of prostate cancer as the species. As explained below, and in light of the declaration of Anjali Jain filed herewith,

Hedvat *et al.* is not prior art under §102(a). In an effort to advance prosecution, Applicants will move forward with prosecution on the elected species of prostate cancer. However, Applicants do not concede to the merits of the Examiner's Restriction Requirement and reserve the right to petition.

Objections

The specification was objected to as containing improperly demarcated trademarks. Applicants have made amendments the specification, shown in the "Amendments to the Specification" section above, to identify trademarks noted therein. As such, Applicants request withdrawal of this objection.

Claim 29 is objected to as being directed in the alternative to the subject matter of a non-elected species of invention. Applicants traverse this rejection. While Applicants do not agree with the merits of the Examiner's objection, in an effort to advance prosecution of the present application, claim 29 has been canceled and thus, the objection is rendered moot.

Priority Claims

The Examiner alleged that the effective filing date of the claims is deemed to be August 27, 2004. Applicants respectfully submit claim 37 properly claims priority to provisional application 60/498,849, filed on August 29, 2003 (see e.g., claim 7 of the provisional application). Thus, claim 37's effective filing date is August 29, 2003.

Rejection under 35 U.S.C. §112, first paragraph, written description.

The Examiner has maintained the rejection of claims 1-10, 29, and 30 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner contends that the claims are directed to a genus of cancers, which are too inadequately described to permit the skilled artisan to distinguish at least a substantial number of the members of this genus. Moreover, the Examiner suggests that the specification fails to describe "resistant" cancer, or more particularly the genus of cancers that are "regulated by HER-kinase axis activation that is resistant

to therapeutic treatments directed exclusively at either the PPAR-gamma pathway or the HER-kinase axis" (Office Action, page 12, par. 1). Applicants traverse this rejection.

While Applicants do not agree with the merits of the Examiner's rejection, in an effort to advance prosecution of the present application, claims 1-10, 29 and 30 have been canceled and thus, the rejection is rendered moot.

Claims 10-19 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement for reasons of record. Applicants respectfully traverse the rejection.

While Applicants do not agree with the merits of the Examiner's rejection, in an effort to advance prosecution of the present application, claims 10-19 have been canceled and thus, the rejection is rendered moot.

Rejection under 35 U.S.C. §112, first paragraph, enablement.

The Examiner has maintained the rejection of claims 10-19, 29, and 30 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement for reasons of record. Applicants respectfully traverse the rejection.

While Applicants do not agree with the merits of the Examiner's rejection, in an effort to advance prosecution of the present application, claims 1-10, 29 and 30 have been canceled and thus, the rejection is rendered moot.

Rejection under 35 U.S.C. §112, second paragraph, indefiniteness.

The Examiner has maintained the rejection of claims 1-10, 29, and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, according to the Examiner, it is not evident which agents are "HER2-kinase axis inhibitors" and which are not. Applicants traverse this rejection.

While Applicants do not agree with the merits of the Examiner's rejection, in an effort to advance prosecution of the present application, claims 1-10, 29 and 30 have been canceled and thus, the rejection is rendered moot.

Claims 10-19 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record. Applicants respectfully traverse the rejection.

While Applicants do not agree with the merits of the Examiner's rejection, in an effort to advance prosecution of the present application, claims 10-19 have been canceled and thus, the rejection is rendered moot.

Rejection under 35 U.S.C. §102

The Examiner has maintained the rejection of claims 10-19 and 29-33 under 35 U.S.C. 102(a) as being anticipated by Hedvat *et al.* (previously cited) for reasons of record. Applicants traverse this rejection.

An applicant's disclosure of his or her own work within the year before the application filing date cannot be used against him or her under §102(a). MPEP §2132.01 (citing *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982)). As such, in instances wherein the applicant is one of the co-authors of a publication cited against his or her application, the publication may be removed as a reference by submission of a specific declaration by the applicant establishing that the article is describing an applicant's own work. Id.

Applicants submit that the priority dates of the pending claims are August 29, 2003 and August 27, 2004. Applicants further submit that Hedvat *et al.*, published June 2004, is not prior art under §102(a). Submitted herewith is a declaration by one of the applicants, Anjali Jain, which shows that to the extent that the instant invention is described in Hedvat *et al.*, it describes solely the work of Michael Hedvat, David Agus and Anjali Jain. The additional named authors in Hedvat *et al.* are co-authors of the article, but are not co-inventors in the present application. Accordingly, Hedvat *et al.* is not prior art under §102(a). Applicants respectfully request reconsideration and withdrawal of the rejection under §102(a).

The Examiner has maintained the rejection of claims 10-12 under 35 U.S.C. 102(b) as being anticipated by Mitsiades *et al.* (previously cited). Applicants respectfully traverse the rejection.

While Applicants do not agree with the merits of the Examiner's rejection, in an effort to advance prosecution of the present application, claims 10-12 have been canceled and thus, the rejection is rendered moot.


Rejection under §103(a)

The Examiner has maintained the rejection of claims 10 and 15-19 under 35 U.S.C. 103(a) as being unpatentable over Mitsiades *et al.* for reasons of record. Applicants traverse this rejection.

While Applicants do not agree with the merits of the Examiner's rejection, in an effort to advance prosecution of the present application, claims 10, and 15-19 have been canceled and thus, the rejection is rendered moot.

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. If for any reason Examiner finds the application other than in condition for allowance, Examiner is requested to call the undersigned attorney at the Los Angeles telephone number (213) 633-6800 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,
David B. Agus *et al.*
DAVIS WRIGHT TREMAINE LLP

By 
Linda B. Truong, Esq.
Registration No. 56,461

865 South Figueroa Street, Suite 2400
Los Angeles, CA 90017-2566
Phone: (213) 633-6800
Facsimile: (213) 633-6899